

REMARKS

Status of the claims

Claims 1-6, 8, 14-19, 21-26, 28, 34-37, 43-44 and 50-51 are pending in the application. Claims 2-6, 8, 14-19, 21-26, 28, 43-44 and 50-51 are withdrawn from consideration. Claims 1 and 34-37 are rejected. No claims have been amended. No new matter has been added.

The 35 U.S.C. §102 rejection

Claim 1 stand rejected as being anticipated by **Unger et al.** (US 2002/0099356). The Applicants respectfully traverse this rejection.

The Examiner states on page 2 of the Office Action that **Unger et al.** disclose a device comprising an actuator (paragraph 66) for driving an abrasive surface (16), a container adapted to deliver an abrasive material (20); a reservoir adapted to contain a pharmaceutical (12); and a permeable member (22). Applicants respectfully disagree.

The Applicants submit that the claimed invention comprise an actuator having a surface adapted to contact an abrasive material, a means for driving the actuator at a high frequency, a container connected to the device having an opening adapted to deliver an abrasive material to the tissue or to collect ablated tissue or other biomolecule, a reservoir containing a pharmaceutical and a permeable membrane adapted to controllably release the pharmaceutical. In contrast, **Unger et al.** teach an iontophoresis device with microneedles (item 16) which may vibrate and comprise a semi-permeable (paragraph 67) drug reservoir (item 12), an acoustic transducer (item 14) and driving circuitry (item 18) (paragraph 66).

In order to anticipate a claim, a single reference must recite each and every element on the pending claim. The Applicants submit that **Unger et al.** does not teach a container which is connected to the device as recited in the instant claims. At least in part, the presence of this container demonstrates the novelty of the claimed invention as it shows the wholly different approaches to delivering drugs.

The device of **Unger et al.** utilize sonic energy to create pores in the skin membrane to increase its permeability to drugs and does not create any waste products. By contrast, the claimed invention ablates tissue by the lateral movement of the abrasive material. Thus the container may have several functions such as encasing the abrasive material or collecting the ablated tissue or biomolecules.

In order for an anticipation rejection to be valid, a single reference must teach each and every element of the pending claim. The Applicants submit that **Unger et al.** fails to teach a container as recited in the instant claims. In view of the arguments presented herein, the Applicants request that the rejection of claim 1 under 35 U.S.C. §102 be removed. The Applicants believe that claim 1 is now in condition for allowance.

The 35 U.S.C. §103 rejection

Claims 34-37 stand rejected as being unpatentable over **Unger et al.** and further in view of **Eggers** (USPN 6,066,134). The Applicants respectfully traverse this rejection.

The Examiner states on page 3 of the Office Action that while **Unger et al.** does not explicitly disclose monitoring feedback using an electrical property, **Eggers** teaches monitoring feedback using a heartbeat to perform a safe ablation procedure and for monitoring a thermal property using infrared sensors. The Examiner also states that the use of an infrared detector and controller to analyze the data from an energy source and detector is inherent in the disclosed device because it measures temperature. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Eggers** in the device of **Unger** to increase the safety of the ablation procedure for better patient outcome and/or to maintain safe operating temperatures.

In order for an obviousness rejection to be valid, the combined references must explicitly or inherently teach all the elements of the pending claim. Furthermore, in order to combine two or more references, there must be reasonable

expectation of success. The Applicants submit that the instant claims are drawn to a device that ablates tissue to increase permeability of a drug and has a feedback control means to monitor the change in electrical properties of the tissue. As mentioned by the Examiner, **Unger et al.** does not teach monitoring feedback using electrical property of tissue. This deficiency is not remedied by **Eggers** which simply teaches the monitoring of heartbeat so that voltage pulses which are used to ablate heart tissue may be timely applied with the contractions of the heart. There is no hint or suggestion in **Eggers** to monitor the change in electrical properties of tissue as recited in the instant claims. Thus the combination of **Unger et al.** and **Eggers** would not teach the instant invention to a person of ordinary skill in the art. Furthermore, the Applicants submit that there is no motivation to combine the references since **Unger et al.** teach delivery of drug across skin membrane and monitoring the heartbeat would not provide the device of **Unger et al.** with any safety advantage.

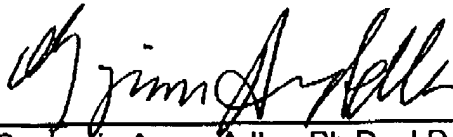
In view of the arguments presented herein, the Applicants request that the rejection of claims 34-37 under 35 U.S.C. 103 be removed. The Applicants believe that claims 34-37 are now in condition for allowance.

This is intended to be a complete response to the Office Action, mailed September 3, 2008. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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